87. The method of claim 86, wherein said selected rate of rise provides a square shaped pressure waveform.

88. The method of claim 86, wherein said selected rate of rise provides a square shaped pressure waveform with minimal ringing.

89. The method of claim 86, wherein said rate of rise is selected adaptively by evaluating a plurality of rates of rise.--

REMARKS

The specification has been amended to include a reference to prior application Ser. No. 08/516,478, filed on August 17, 1995, as required by 37 CFR 1.78(a)(2).

Claims 1-36 have been cancelled and claims 37-89 have been added. The pending application now contains claims 37-89.

In the prior application, Claims 37-85 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kanesaka in view of Watson et al. These claims have been amended in the present application and applicants respectfully submit the following remarks.

Claim 37 recites a "method of operating a ventilator." The method recited in claim 37 includes "inputting, into [a] control device, data representing only a body length of a patient to be ventilated; calculating, in the control device, at least one ventilation parameter, wherein said calculating step consists essentially of calculating the at least one ventilation parameter based upon the input body length of the patient; and providing ventilation in accordance with the calculated at least one ventilation parameter." Independent claims 48 and 66 also recite methods of operating a ventilator including the

step of "inputting, into [a] control device, data representing only a body length of a patient to be ventilated." Claim 48 also includes the step of "calculating, in the control device, at least one ventilatory limit, wherein said calculating step consists essentially of calculating the at least one ventilatory limit based upon the input body length of the patient." Claim 66 also includes the step of "calculating, in the control device, at least one ventilation alarm setting, wherein said calculating step consists essentially of calculating the at least one ventilation limit based upon the input body length of the patient."

Applicants respectfully submit that Kanesaka and Watson et al., whether taken alone or in combination, fail to teach or suggest a method of operating a ventilator wherein a ventilator's control device uses only a patient's body length to calculate at least one ventilation parameter, ventilatory limit or ventilation alarm setting as recited in, respectively, claims 37, 48 and 66.

Initially, as noted in an Amendment filed by the applicants in the prior application on January 13, 1999, Kanesaka relates to ventilators and Watson et al. to a rebreathing anesthesia system. These systems are different. In particular, there is no need to control the flow of fresh gas as disclosed by Watson et al. in a ventilator such as the type disclosed by Kanesaka. Thus, the prior art does not provide adequate motivation to modify Kanesaka in view of Watson et al. in the manner proposed in the Office action.

Moreover, presuming for the moment that motivation exists to combine the references, applicants respectfully submit that the combination does not teach or disclose a method of operating a ventilator wherein a ventilator's control device uses only a patient's body length to calculate at least one ventilation parameter, ventilatory limit or ventilation

alarm setting as recited in claims 37, 48 and 66, respectively. Applicants have developed unique formulas for the ideal tidal volume and flow rate settings. The formulas were developed using data from 95 patients and a polynomial regression analysis that determined appropriate coefficients for the formulas (Specification page 30, line 24 to page 31, line 19). Specifically, from the data gathered, applicants have developed an algorithm for estimating tidal volume based solely on body length, namely Tidal Volume (L) = 0.21 + $0.0037X + 0.0000108X^2$, where X is body length in centimeters. Likewise, the applicants have developed an algorithm for estimating ventilation rate, namely Rate (breaths/minute) = $40.59 - 0.36X + 0.000996X^2$, where X is body length in centimeters. Other factors such as sex, age, weight, body surface area, etc. were not factored into this analysis.

Thus, the calculations are only based upon the body length of the patient. As noted in the Specification, the use of body length is preferred and much safer to the patient than the alternative and manual techniques, particularly since it is more readily obtainable. Errors due to miscalculations or an inexperienced technician, which could lead to pulmonary barotrauma, respiratory acid-base disturbances or physiologic abnormalities are avoided because only one simple parameter, i.e., body length, must be input for the present invention to automatically calculate appropriate ventilation parameters, ventilatory limits or ventilation alarm settings (Specification page 29, line 11 to page 30, line 16; page 32 lines 19 to 23; and page 33, lines 13 to 25).

Kanesaka, by contrast, teaches manual settings that are based on patient weight, height, sex, and other clinical conditions. The fresh gas flow constant calculated in the Watson et al. system is related to body surface area as determined by a patient's height and

weight. Weight, sex and other clinical conditions are not factored into the formulas of the present invention, which are based solely on one input parameter, i.e., the patient's body length. Accordingly, a key feature of the claimed inventions is neither taught nor suggested by the cited references. Consequently, claims 37, 48 and 66 of the present application are allowable over the previously cited prior art.

Claims 38-47 depend from claim 37 and are allowable along with claim 37. Claims 49-65 depend from claim 48 and are allowable along with claim 48. Claims 67-85 depend from claim 66 and are allowable along with claim 66.

Claims 86-89 recite "providing a ventilator having a mechanism for adaptively setting a rate of airway pressure rise during pressure support ventilation; providing a second ventilated breath with a second rate of rise of inspiratory pressure; evaluating each of said ventilated breaths; selecting the rate of rise that provides the desired pressure waveform; and providing ventilation using said selected rate of rise." None of these features are taught or suggested by the cited prior art references.

Allowance of the application is solicited.

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Respectfully submitted,

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